

REMARKS

I. Introduction

The Office Action mailed September 3, 2008, has been carefully considered. The present Response is intended to be a complete response thereto and to place the case in condition for allowance.

II. Status of the Claims

Claims 1-27, 29-39, 45-121 are pending. Claims 28 and 40-44 have been cancelled. Claims 1-22, 30, 32, 33, 46-116, and 121 have been withdrawn from consideration by the Examiner as being drawn to non-elective invention or species.

III. Summary of the Office Action

In the office action, the Examiner rejected

- 1) claims 23-29, 31, 14-39, 44, 45, and 117-118 under 35 U.S.C. § 103(a) as being obvious over Marchant (U.S. Patent Application Publication No. 2002/0068087) in view of Viegas et al. (U.S. Patent Application Publication No. 2003/0143274); and
- 2) claims 24, 26-29, 31, and 34-39 under 35 U.S.C. § 103(a) as being obvious over Sawhney (U.S. Patent No. 6,818,018) in view of Marchant.

No rejection has been applied to claims 119 and 120. Therefore, Applicants respectfully submit that these claims are allowable if rewritten to be in independent form.

IV. Argument

Applicants respectfully traverse the rejections for the following reasons:

Marchant and Viegas et al., taken alone or in combination, do not disclose every element of the claimed invention. Marchant fails to disclose the step of “introducing a reversible hydrogel system in solution into the capsular bag of an eye,” as recited by independent claim 23. None of the cited references even mentions the capsular bag of an eye. Marchant discloses bioadhesive hydrogels with degradable crosslink “for use inside the body.” See paragraph [0021]. “For use inside the body,” however, is not the same as in the capsular bag. The invention of Marchant requires making the hydrogel and then using it in the body, not gelating the hydrogel in the body (*in situ* gelation). The applications recited by Marchant do not contemplate *in situ* gelation. For example, the methods recited in paragraphs [0048]-[0050] and in paragraphs [0053]-[0055] recite a step of isolating the crosslinked composition. *In situ* gelation would not allow for the isolation of the crosslinked composition as the gel would already be in the body and its further purification (isolation) is not possible. Therefore, because the gelation of Marchant occurs outside of the body, this reference does not teach the step of “introducing a reversible hydrogel system in solution into the capsular bag of an eye.”

Additionally, Marchant discloses a degradable hydrogel. This is not compatible with the present invention where the gel is used as a lens replacement. A degradable gel clearly is not desirable for use as a lens replacement as it is not desirable to have a patient go through surgery for lens replacement only to have the new lens degrade. This clearly teaches away from the present invention.

The Examiner relies on Viegas et al. to show uses of *in situ* formed gels. However, none

of these uses pertains to lens replacement. In paragraphs [0049] and [0051] Viegas et al. disclose the used of the hydrogel as a corneal protective composition. This corneal protective composition presumably involves covering the cornea with the hydrogel; however, this is not the same as introducing a reversible hydrogel solution “into the capsular bag of the eye.” Thus, the combination of Marchant and Viegas et al does not disclose every element of the claimed invention.

With regard to Sawhney in view of Marchant, neither reference discloses the introduction of a reversible hydrogel solution into the capsular bag. None of the references even mentions the capsular bag of the eye. The deficiency of Marchant is discussed above. The only application disclosed by Sawhney that relates to the eye is in Example 7 (Columns 23-24) where the hydrogel is used as corneal shields. The reference suggests making a contact lens from the hydrogel and rehydrating it for use as corneal shields. It is important to note that corneal shields “‘hug’ the eye like a contact lens and disappear after approximately 12 hours to 3 days.” Column 23, lines 63-65. Hugging the eye “like a contact lens” does not involve introducing the hydrogel solution into the capsular bag of the eye.

Sawhney also teaches away from the present invention by disclosing that his corneal shields “disappear after approximately 12 hours to 3 days.” This is contrary to the present invention where it is not desirable to have a patient go through surgery for lens replacement only to have the new lens disappear after 12 hours to 3 days.

In the Final Office Action, the Examiner alleges that Marchant in paragraph [0015] “discloses introducing the gel forming solution into the eye ... and using the solutions [*sic*] to deliver actives.” Final Office Action, page 4. For the Examiner’s convenience, paragraph [0015]

of Marchant is as follows:

[0015] Polymeric drug carriers have been designed to attempt optimize the delivery of therapeutic agents orally (i.e., injectable and/or within the oral cavity), renally (e.g., suppositories), intravenously (i.e., through the bloodstream), ocularly (i.e., in the eyes), nasally (e.g., nasal sprays), vaginally, from surgically implanted polymeric depots, and other known treatment methods.

This paragraph cannot reasonably be said to disclose introducing a reversible gel solution into the capsular bag of the eye. There is no hint or suggestion to introduce a reversible gel solution into the capsular bag of the eye. Ocular delivery of drugs by polymeric drug carriers cannot reasonably be read to disclose the step of introducing a reversible gel solution into the capsular bag of the eye. Therefore, the combination of Sawhney and Marchant fails to disclose every element of the claimed invention.

Because none of the cited references discloses or suggests the step of “introducing a reversible hydrogel system in solution into the capsular bag of an eye” as recited by independent claim 23, their combination cannot render the present claimed invention obvious within the meaning of 35 U.S.C. § 103. Accordingly, Applicants respectfully request withdrawal of the rejections.

V. Conclusion

Applicants have responded to the Final Office Action mailed September 3, 2008. All pending claims are now believed to be allowable and favorable action is respectfully requested.

In the event that there are any questions relating to this Response or to the application in general, it would be appreciated if the examiner would telephone the undersigned attorney concerning such questions so that the prosecution of this application may be expedited.

Please charge any shortage or credit any overpayment of fees to BLANK ROME LLP, Deposit Account No. 23-2185 (111828.0110). In the event that a petition for an extension of time is required to be submitted herewith and in the event that a separate petition does not accompany this response, Applicants hereby petition under 37 C.F.R. 1.136(a) for an extension of time for as many months as are required to render this submission timely.

Any fees due are authorized above.

Respectfully submitted,

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